APR - 3 2009

Chapter III 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: K083466

1. Device Information

Device Common Name: Oximeter
Device Trade/Proprietary Name: MD 2000A Vital Sign Monitor

Classification Information:
(1) Classification Name: Oximeter
(2) Regulation Number: 870.2700
(3) Product Code: DQA
(4) Class: II
(5) Review Panel: Anesthesiology

2. Submitter Information

Manufacturer:
Beijing Choice Electronic Technology Co., Ltd.
Room 1127-1128 Building B, Bailangyuan
Fuxing Road , No. A36,Beijing, China 100039

Contact Person of the Submission
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Shanghai, China 20020
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Email: Diana.hong@mid-link.net

3. Device Description

The device works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of

light source is 660 nm, which is red light; the other is 940 nm, which is ultra red light.

Skin, bone, tissue, and venous vessels normally absorb a constant amount of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.

The applicant device of MD2000A Vital Sign Monitor is the Desktop Pulse Oximeter Monitor, which mainly function are measurement, display, alarm, data storage.

Measurement function

That's the mainly function of the device, which use the method describe above to measure the SpO2 value and Pulse Rate value of lay user.

Display function

The display function of the device have two display area dividually, the one display area use the LCD display mode, which displays the date & time, battery capacity indicator, SpO2 and PR alarm limit value, ID number, auditory alarm state indication, pulse beep state indication and pulse plethysmogram.

The another display area use the LED display mode, which displays the SpO2 value, PR value and blip bar.

Alarm function

The applicant device has there-level priorities alarm, they are High priority, Medium priority and Low priority.

Each alarm of device contains VISUAL and AUDIBLE alarm.

Data storage function

The measured record is stored automatically every four seconds. The monitor can store 72 hours records.

The new record will be stored with the initial records being erased when the stored records are full.

The device also has the function as "record review", "SpO2 Trend Review" and "PR Trend review", the user can use those function to review stored data easily.

Power

The applicant device has two kinds of power supply as AC power supply and Battery power supply.

The AC power supply complies with following specification: 100-230 (VAC),

50/60 (Hz).

The battery used in the applicant device is a Ni-MH battery with 7.2V d.c. output, the battery be able to recharged by AC power supply.

The battery be able to provide the power to make the device run in normal, when the AC power supply connected, the battery will turn into charge state from power supply state automatically.

The applicant device have 2 models detachable sensor as the accessory, they are listed below:

M-50A (for Adult)

M-50C (for Pediatric and Neonate)

The applicant device is not for life-supporting or life-sustaining, not for implant. The device is not sterile and does not need sterilization or re-sterilization. The device is for prescription. The device does contain drug or biological product.

4. Intended Use

The MD2000A vital sign monitor is portable device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial haemoglobin (SpO_2), and pulse rate of adult, pediatric and neonate patients via finger in hospitals, medical facilities, and subacute environments. The vital sign monitor is intended for spot-checking and/or continuous monitoring of patients, the sensor of device is reusable

5. Substantially Equivalence Determination

The applicant devices **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant devices are determined as safe and effectiveness.

6. Test Summary

The device is electrically operated and the electrical safety and electromagnetic compatibility following IEC 60601-1 and IEC60601-1-2 were conducted.

The Clinical Test Report following ISO 9919:2005, Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use are conducted in the Clinical Laboratory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Shanghai, CHINA 20020

APR - 3 2009

Re: K083466
Trade/Device Name: MD 2000A Vital Sign Monitor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 27, 2009
Received: March 3, 2009

Dear Ms. Kong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

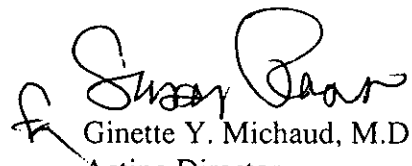
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication For Use

510(k) Number (if known): Pending K083466

Device Name: MD 2000A Vital Sign Monitor

Indications for Use:

The MD2000A vital sign monitor is portable device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial haemoglobin (SpO_2), and pulse rate of adult, pediatric and neonate patients via finger in hospitals, medical facilities, and subacute environments. The vital sign monitor is intended for spot-checking and/or continuous monitoring of patients, the sensor of device is reusable.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K083466